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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,507	12/05/2003	Tadao Michishita	246111US2DIV	7835
22850	7590	10/06/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WONG, EDNA	
			ART UNIT 1753	PAPER NUMBER

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,507

Applicant(s)

MICHISHITA ET AL.

Examiner

Edna Wong

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/720,806.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/13/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

This is in response to the Amendment dated September 13, 2004. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Drawings

The replacement sheet of the drawing was received on September 13, 2004. This drawing is approved by the Examiner.

Specification

I. The abstract of the disclosure has been objected to because the abstract is more than 150 words and more than 1 paragraph long.

The objection of the abstract of the disclosure has been withdrawn in view of Applicants' amendment.

II. The disclosure has been objected to because of minor informalities.

The objection of the disclosure has been withdrawn in view of Applicants' amendment.

Claim Objections

I. Claims **12, 23 and 45** have been objected to because of minor informalities.

The objection of claims 12, 23 and 45 has been withdrawn in view of Applicants' amendment.

II. Claim **13** has been objected to under 37 CFR 1.75(c) as being in improper form.

The objection of claim 13 under 37 CFR 1.75(c) has been withdrawn in view of Applicants' amendment.

Claim Rejections - 35 USC § 112

Claims **12-49** have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 12-49 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicants' amendment.

Allowable Subject Matter

The indicated allowability of claims 11-49 is withdrawn in view of the newly discovered reference(s) to **Sato et al.**, "Effect of Wavelength on the Formation of 1 α -Hydroxyprevitamin D₃ in the Ultraviolet Irradiation of Cholesta-5,7-Diene-1 α , 3 β -Diol and the Use of a Filter Solution in the Photochemical Reaction in the Synthesis of 1 α -Hydroxyvitamin D₃ (1980)". Rejections based on the newly cited reference(s) follow.

Response to Amendment

Specification

The disclosure is objected to because of the following informalities:

page 1, line 6, in the "Cross-Reference to Related Applications", the words -- ,
now abandoned -- should be inserted after the number "2001".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **11-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over
Sato et al., "Effect of Wavelength on the Formation of 1 α -Hydroxyprevitamin D₃ in the
Ultraviolet Irradiation of Cholesta-5,7-Diene-1 α , 3 β -Diol and the Use of a Filter Solution
in the Photochemical Reaction in the Synthesis of 1 α -Hydroxyvitamin D₃ (1980)" in
combination with **Nagano et al.** (US Patent No. 5,748,288).

Sato teaches a process for preparing a vitamin D derivative, comprising:

(a) providing an ultraviolet irradiation apparatus for photochemical reactions,
which comprises an ultraviolet radiation-emitting lamp (= Xe arc lamp), an optical

system on which light from the ultraviolet radiation-emitting lamp is struck (= grating) and which emits ultraviolet rays having a specific wavelength (= 200-700 nm);

(b) irradiating a solution of a provitamin D derivative (= a solution of 1α -OH-7-DHC in ethanol) with the ultraviolet rays having the specific wavelength emitted from the ultraviolet irradiation apparatus to cause a photochemical reaction to the provitamin D derivative solution, thereby forming a previtamin D derivative (= 1α -OH-pre-D₃); and

(c) subjecting the previtamin D derivative to a thermal isomerization reaction (= heated at 45°C for 24 hours) to prepare the vitamin D derivative (= 1α -OH-D₃) [page 545, "Summary"; and pages 547-578, "UV irradiation of 1α -OH-7-DHC with monochromatic UV light"].

The provitamin D derivative is a compound represented by the following general formula 1 (= 1α -OH-7-DHC), the previtamin D derivative is a compound represented by the following general formula 2 (= 1α -OH-pre-D₃), and the vitamin D derivative is a compound represented by the following general formula 3 (= 1α -OH-D₃), wherein R is a lower alkyl group having 1 to 10 carbon atoms; R¹ is a hydroxyl group; R² is a hydrogen atom; R³ is a hydroxyl group; R⁴ is a lower alkyl group having 1 to 10 carbon atoms and X is -CH₂-CH₂- (page 545, "Summary"; and pages 547-578, "UV irradiation of 1α -OH-7-DHC with monochromatic UV light").

The irradiation comprises irradiating a solution of the provitamin D derivative represented by the general formula I (= a solution of 1α -OH-7-DHC in ethanol) with the ultraviolet rays to cause a photochemical reaction of the provitamin D derivative

solution, thereby forming the previtamin D derivative represented by the general formula 2 (page 545, "Summary"; and pages 547-578, "UV irradiation of 1 α -OH-7-DHC with monochromatic UV light").

In the general formulae 1, 2 and 3, R³ is a hydroxyl group and X is -CH₂-CH₂- (i.e., if only counting two of the -CH₂'s in the (CH₂)₃ of chloestra-5,7-diene-1 α ,3 β -diol as "X").

In the general formulae 1, 2 and 3, R¹ is a hydroxyl group.

In the general formulae 1, 2 and 3, R² is a hydrogen atom.

Sato does not teach a quartz rod on which the ultraviolet rays having the specific wavelength from the optical system are struck.

However, Nagano teaches that an optical integrator is a quartz rod (col. 3, line 55 to col. 4, line 22; and Fig. 1).

Thus, the invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process of Sato with a quartz rod on which the ultraviolet rays having the specific wavelength from the optical system are struck because Sato teaches that the spectroirradiator comprises an integrator to assess quantum of irradiated energy (page 547, 21-26). Nagano teaches that an optical integrator is a quartz rod (col. 3, line 55 to col. 4, line 22;

and Fig. 1). Thus, it would have been well within the skill of the ordinary artisan to have used a quartz rod disclosed by Nagano as the integrator disclosed by Sato.

Furthermore, it has been held that the selection of a known material based on its suitability for its intended use supports a prima facie obviousness determination. See MPEP § 2144.06 and § 2144.07.

As to the variables of R, R¹, R², R³ and/or X in claims 14-23, 27-31 and 35-49, these variables do not react in the photochemical reaction. They are present in starting in the compound from the beginning to the end. Therefore, it is well within the skill of the ordinary artisan to have substituted similar variables in the compound and reasonably expected a similar photochemical reaction, unless proven otherwise.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edna Wong whose telephone number is (571) 272-1349. The examiner can normally be reached on Mon-Fri 7:30 am to 3:30 pm, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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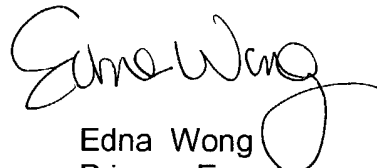
published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Edna Wong". The signature is fluid and cursive, with the first name "Edna" and last name "Wong" clearly distinguishable.

Edna Wong
Primary Examiner
Art Unit 1753

EW
September 30, 2004